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6 December 2011

Mr. Ted Wackler, Deputy Chief of Staff
Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Via e-mail: bioeconomy@ostp.gov

Ref: Request for Information: Building a 21st Century Bioeconomy

Dear Deputy Chief Wackler:

On behalf of ArborGen Inc. and its employees around the globe, we would like to commend President Obama and the Office of Science and Technology Policy for taking this extraordinary initiative to build a 21st Century National Bioeconomy. This process of bringing together the thoughts and concerns of citizens and companies in the United States, who can support critical technologies through their research, development and commercialization skills, is an important first step in successfully reaching the Administration's goal of reducing our nation's dependence on non-renewable fossil fuels.

As part of our response, we will provide observations on the current regulatory process and offer some suggestions that could both make an immediate impact spurring the U.S. bioeconomy in the short-term while exploring issues that will require some long-term planning and adjustments. In this document, we will explore the following issues and topics in-depth:

- The importance of trees and biotechnology in emerging landscape of today and their potential transformative impact on advancing our nation's bioeconomy for the 21st Century;
- The difficulty and challenges of the current permitting process, which creates and insurmountable economic barrier for companies, from startups to even well-funded ventures;
- Recommendations on making permitting process more efficient, such as the increased usage of existing data to build more certainty and predictability in the NEPA process;
- The establishment of a "learn-as-you-grow-track" for non-food crops such as trees to provide economic relief and certainty during the permitting process.

By addressing these issues, we believe that the U.S. would be able to create a model that is economically viable and will unlock the economic and environmental benefits of biotechnology trees while maintaining a robust and comprehensive permitting process that will protect and preserve our natural resources.

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ArborGen's Role in a 21st Century Bioeconomy

ArborGen is a foundational company for a bioenergy economy, providing the roots and stems of an industrial raw material that is clean, environmentally beneficial, renewable and highly sustainable: commercial trees. Robust tree seedlings, bred with the best possible genetics, impact a National Bioeconomy at almost every level. Trees are a source of raw material for construction, furniture and paper, as well as for pharmaceuticals, both active and inert ingredients, and an endless array of cellulose-based materials. Trees provide a source of energy, sequester carbon and purify water. Trees are fundamental building blocks for community economies, jobs and industry. Purpose grown trees help manage precious resources, provide ecosystem services proportional to longer-lived plantations, help meet much needed conservation goals, and provide renewable raw materials for industrial use.

ArborGen agrees that 21st century advances in biological research and technologies are poised to return tremendous public benefits. At ArborGen we are perfecting methods through advanced breeding and biotechnology for improving wood quality; unlocking the raw cellulose in wood for improved manufacturing purposes such as energy and paper, and shortening time to maturity of high industrial value trees species such as Eucalyptus to ensure a sustainable supply under high and increasing demand; and helping responsibly integrate such species into the U.S. landscape.

ArborGen's technology platform represents more than 50 years of collective research and development and more than $200 million in capital expenditures, a level of dedication unrivalled in the forestry sector world-wide. With a focus on improving productivity and shortening growth cycles through conventional tree breeding and biotechnology, ArborGen has been focused on meeting an increasing global demand for traditional wood and paper products as well as providing sustainable feedstock solutions for renewable energy for more than a decade.

The world's population is now at seven billion people and expected to reach nine billion by 2050. As such, the global land base will remain our most critical and precious non-renewable resource. Maximizing the productivity of every acre designated for growing trees for human needs including food, wood, fiber and energy, and ensuring that each purpose-grown tree is planted for its ideal end-use will require new methods of cultivation, breeding, harvest and processing, as well as an advanced public acceptance of purpose-grown trees.

ArborGen is finding ways to unlock the potential of the tree by identifying and improving traits that meet important commercial needs. The lumber and pulp and paper industries, for example, have invested millions of dollars over the last century to breed trees for their ability to produce high value lumber first, and second to feed into mills for the extraction of fibers to make paper products. These programs have focused on developing a tree that most effectively meets the needs for wood and fiber. Loblolly pine is the prime example of a tree that has been significantly improved for a purpose by a responsible industry working to perfect a raw material to help keep pace with human consumption rates. Additionally, the tree is a storage container for carbon, even when the lumber is milled, the paper is rolled and furniture is crafted. When burned for energy, the carbon release is equivalent to that of the carbon stored, making the process carbon neutral. And trees are renewable. There is no plant species of greater value than the tree.

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Why Trees Are the Foundation for a 21st Century Bioeconomy

The challenge for ArborGen, as well as for a bioeconomy that offers biomass-based energy, is that the crops best suited to cellulose production for biomass – short rotation woody species such as Eucalyptus– bring new challenges to regulators. Though ArborGen believes that plants should all be reviewed equally and not singled out for scrutiny because one species is different from another, it is inevitable that perennials and long-lived species like trees must factor in the complexity of time. It simply takes longer for some species to reach maturity, which in turn creates longer timelines for deregulation and significantly higher proportional costs than is true of annuals such as corn and soybeans.

With the emergence of genomics, gene mapping, and genetic engineering, scientists are able to learn more about the mechanics of tree breeding than ever before and are rapidly striving to domesticate species for commercial purposes. Advanced breeding technologies such as cloning allow for standardization, which improves harvest and production efficiencies. Controlled pollination and hand selection have improved germplasm, improving disease resistance, straightness and branching of trees and improving per acre productivity. Technologies such as genetic engineering are now being applied to advance the performance of the tree for specific purposes, such as bioenergy, biofuels, pelleting and charcoal, as well as for improved growth, processability and stress tolerance.

In the United States, industrial production is limited by accessible hardwood trees, which provide needed high quality cellulose, a high-demand industrial raw material. They also have a higher BTU value than softwood making them preferred for energy production. Because hardwoods grow at a ponderous rate, are notoriously difficult to cultivate and are highly adapted to specific geographic locations, soil types and climates, the United States forestry industry has been only marginally successful at cultivating hardwood species in purpose-grown stands. Therefore, the greatest share of hardwoods for industrial use are harvested from forests managed to regenerate naturally, adding sustainability to the process, but not much toward supply predictability or harvest efficiency.

While hardwood species of high industrial value, such as cottonwood and aspen, are native to the United States, no native species has proven to be a solution equal to the value of an Australian native species, the Eucalyptus. Like the soybean (native to central China), this plant has a proven value well beyond its native habitat, and domestication for commercial purposes has proven to be of immense social, economic and environmental value. In the tropical and sub-tropical climate of Brazil for example, producers have adapted to growing non-native Eucalyptus species on what was formerly agricultural land. Cultivation of these trees has changed the economy of that country, creating a global leader in hardwood pellet, charcoal and cellulose production and export. At the same time, the purpose-grown Eucalyptus stands in Brazil are helping relieve pressure to harvest material for wood, fiber and energy from precious hectares of rain forest in this South American nation.

The value of the Eucalyptus species is so widely recognized that it became one of the first trees species to be mapped and sequenced through genomics. In an article published in *Biology & Nature* on May 12, 2011, Professor Zander Myburg[1] from the Department of Genetics and the Forestry and Agricultural Biotechnology Institute (FABI) at the University of Pretoria (UP) – in collaboration with the United States Department of Energy (DOE) Joint Genome Institute (JGI) – wrote that the genome

[1] http://esciencenews.com/articles/2011/05/12/eucalyptus.tree.genome.deciphered

sequence of the forest tree species, *Eucalyptus grandis* had been completed. In this article, Professor Myburg explains why this genomic sequencing project is of significant value to society:

> *Research is done on plants rich in cellulose (the main chemical component of wood), because glucose - the building block of cellulose - can be used in the production of biofuels and other renewable products. Eucalyptus trees grow very fast and can deliver the necessary biomass for making these bioproducts. Trees are advantageous when it comes to producing biomass. Unlike seasonal crops, they can be harvested year-round to supply a stable supply of biomass. In general they also don't compete with food crops. In addition, wood processing is well established in the pulp and paper industry. Similar processing can be used to isolate the cellulose from the wood for biofuels and other products.*

Because of their intolerance to cold temperatures, however, a very few varieties of commercially valuable Eucalyptus have been restricted to production in the southern most reaches of Florida and Texas. Because of the limited geography in which they can be cultivated, Eucalyptus has not been a viable alternative for providing a sustainable, reliable hardwood supply for U.S. industrial purposes.

ArborGen has a proven technology that can improve the cold tolerance of Eucalyptus, making it a viable species for purpose-grown hardwood stands in the Southern United States. In addition, ArborGen has been successful at modifying lignin ratios, a key technology to help unlock the valued cellulose trapped inside the structure of the tree. The U.S. National Renewable Energy Laboratory using an ArborGen modified Eucalyptus, has found that this tree releases more than twice the usual amount of sugar, making it a promising option as a biomass feedstock for liquid fuel[2].

Time and Scale Create Unique Barriers to the Deregulation of Modified Perennial and Long-Lived Organisms

ArborGen has been working toward commercialization of a hardwood Eucalyptus species engineered to improve its ability to tolerate freezing so that it can be grown in the Southern United States. Throughout the process of working through permits, gathering data, conducting studies and moving toward deregulation, ArborGen has experienced that when a species or technology is truly innovative and unfamiliar to USDA APHIS' Biotechnology Regulatory Services, it becomes subjected to significant delays in processing, and ongoing requests for additional data.

USDA is rich in institutional knowledge about row crops, with an entire branch of the organization dedicated to agricultural research – USDA's Agricultural Research Service (ARS). Within USDA, expertise also exists on the management of forests, but for public forest lands, not commercial forest lands. The government's institutional knowledge of specific species of trees, of diseases and pests of trees all exist in the United States Forest Service, but the knowledge related to growing, harvesting and managing commercial scale trees is tangential. The Forest Service's charge is to manage public lands, not to manage a commercial tree farm. Therefore, it is not surprising that when asked to deregulate a tree species modified for its commercial non-food value –ArborGen Freeze Tolerant Eucalyptus – USDA has been unable to call upon the same levels of institutional knowledge to get answers to questions in the same way it could for soybeans, corn or cotton. As a result, ArborGen's permits for field testing of

[2] Anglea Ziebell in a presentation to the 33rd Symposium on Biofuels and Chemicals held in Seattle, Wash., May, 2011.

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Freeze Tolerant Eucalyptus were in review at USDA's Biotechnology Regulatory Service (BRS) longer than any other plant species – 852 days. ArborGen's current permit for additional traits in Eucalyptus is the longest of all permits pending and currently in review at 282 days as of 11/30/2011 (the next longest being just 78 days).

The fact is that *7 Code of Federal Regulations Part 340* is a complex authority, so institutional knowledge and expertise offers an advantage to a familiar modified organism working its way through the regulatory system. It makes sense that for crops such as corn, soybean and cotton, institutional knowledge has helped the regulatory authority focus on the "plant pest risk" of the engineered trait, rather than spending valued time trying to accumulate useful knowledge about non-modified species. However, Freeze Tolerant Eucalyptus has proven that when that institutional knowledge does not exist, the permits and applications for the product are placed into a category that requires greater scrutiny and significantly longer timelines. Scrutiny is not, and should not, be a concern to any developer but the lack of predictability, evolving data requirements and the scrutiny itself is driving up costs and lengthening timelines, which is creating a significant barrier to success for ArborGen and for scientists who follow.

Lack of institutional data creates a system that invites other agencies to intervene with concerns that color and hamper action by the Biotechnology Regulatory Service. In our experience with Freeze Tolerant Eucalyptus, the Department of Interior intervened, concerned about its lack of institutional knowledge on the species, and attempting to bring its influence to bear earlier in the process of deregulation than has been seen before, at the permit stage. DOI's concerns are about the non-regulated species in general not distinct to the regulated tree. Fortunately, after many months of delays and discussions, DOI conceded that ArborGen's Freeze Tolerant Eucalyptus was not yet at the full commercial stage, but made it equally clear that this species would have to be held to a higher standard than any species previously deregulated.

DOI's desires for more information about Eucalyptus in the United States are valid. It is wise to learn more about this tree because it has been proven to be of such significant value as an industrial raw material. But rather than operating as if there is no knowledge about the species, the government should consider data that already exists in abundance in other countries where this same non-native species is being grown with tremendous success. Global data would firmly prove that where there are potential for negative effects of planting Eucalyptus, this species is easily managed and contained. The problem appears to be that the U.S. would prefer to rely exclusively on U.S.-based data and at large scale. Given the regulatory restrictions imposed prior to deregulation, gathering long term volumes of data for a long-lived species becomes economically prohibitive for small to mid-sized companies.

Equally complex is that in more than two decades of knowledge gained about genetic engineering and the astonishing safety record of biotechnology, the government appears to be less inclined to learn from its own institutional knowledge in this regard. According to testimony[3] from Jim Greenwood, chief executive officer of the Biotechnology Industry Organization, BRS now has substantial evidence to support the safety and efficacy of biotechnology in food crops:

[3] Testimony of the Biotechnology Industry Organization to the Subcommittee on Rural Development, Research, Biotechnology, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives, June 23, 2011

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"Since the first crop developed through modern biotechnology was commercialized more than 15 years ago, U.S. producers have embraced the technology and grown increasing acres of biotech products. According to 2010 figures from USDA's Economic Research Service, 93 percent of soybean and cotton and 86 percent of corn grown in the U.S. were biotech varieties. Producers outside of the U.S. have also successfully utilized biotechnology: in 2010 more than 15 million farmers in 29 countries grew 365 million acres of biotech crops and trees. Nearly 50 percent of these crops and trees were grown by small producers in developing countries where rates of biotech adoption have been steeper than in industrialized nations. The expanding use of agricultural biotechnology throughout the world has made biotechnology the most rapidly adopted agricultural innovation in history"

To be clear, oversight of genetically engineered organisms falls squarely and solely under the Coordinated Framework and the agencies (USDA, EPA and FDA) where expertise in these organisms resides. Other agencies such as the Department of Interior, Department of Energy and the military, may have an interest in what is going on at BRS as biomass crops are being developed, but it is absolutely clear where the regulatory authority is and should reside.

We fully expect to see this exact scenario, intercession on behalf of other agencies, reluctance to utilize global data or call upon non-government expertise, repeated with any perennial species, any species being developed for biomass, and any species that is long-lived. Excessive costs created by delays when agencies have to negotiate with another, rising costs of research to provide additional data, and the built in calculation of the cost of NEPA lawsuits make the current roadmap for deregulation untenable for biomass crops.

Plant Pest Risk Analysis and National Environmental Protection Act

It is not the need for additional meaningful data, nor any lack of respect for the depth of understanding the government seeks that is a concern for ArborGen, it is the seemingly endless and unpredictability of the Plant Pest Risk Analysis, combined with the litigious environment created by application of the National Environmental Policy Act that becomes a barrier to entry for small business.

While ArborGen strongly supports the need for environmental responsibility and controls, the company is significantly burdened by the financial demands of litigation and a leaden regulatory system. Business succeeds on its ability to accurately predict economic outcomes both in the near and long terms. Under the current regulatory framework, our concern is that ArborGen's Freeze Tolerant Eucalyptus will continue to be held up in the system with no end in sight.

Significant delays in deregulation of Freeze Tolerant Eucalyptus have created timidity among investors who would otherwise see ArborGen as a great place to grow their capital. It is impossible for business investors to accept that once a proven technology goes into the regulatory system, their investment goes into a "black hole," with no predictable end in sight and no way to influence the outcome. Such behavior is not acceptable in business, but it is the status quo for our regulatory systems.

Biotechnology Regulatory Services appears to be overwhelmed by multiple aspects of the deregulation of Freeze Tolerant Eucalyptus:

1. Eucalyptus is not native to the United State. Even though non-modified species have been grown in the United States for many decades on thousands of acres with significant success as a mulch crop, the tropical and semi-tropical nature of the tree has limited its growth for successful commercial purposes to the southernmost reaches of Florida. Still, BRS seeks additional data on a broader scale to prove that Freeze Tolerant Eucalyptus is non-invasive.

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2. BRS lacks institutional expertise on commercial hardwood tree species: ArborGen's Freeze Tolerant Eucalyptus is the first commercial hardwood tree to be submitted for deregulation. In addition, institutional knowledge at USDA on commercial tree planting, harvest and marketing is nominal when compared to annual agricultural crops.
3. A reluctance to accept data from other countries where Eucalyptus has been successfully grown on millions of acres for decades. Eucalyptus is among the fastest growing hardwood trees in the world, is grown in more than 90 countries and represents eight percent of all planted forests. A large part of the global supply is concentrated in Brazil, with approximately 3.5 million hectares (a little over 8.5 million acres) in plantations. In 2003, global Eucalyptus pulp demand was eight million tons and it represented 40 percent of the world's hardwood pulp market.
4. Lack of clear guidance from BRS, most likely because of a lack of institutional knowledge or experience with such species, on evaluating perennial, long-lived plants such as trees and grasses.
5. A shift toward a precautionary approach that seeks to require "proving a negative." Whether in response to the European preference for the precautionary principle or excessive precaution promulgated by multiple NEPA lawsuits, BRS has become significantly more cautious in deregulating plants in the last decade, even with those species with which it has great familiarity.

In the case of Freeze Tolerant Eucalyptus, the agency is pushing for data that proves the species is non-invasive, or will not negatively impact hydrology. More than ample data is provided in the petition for deregulation to show that the hybrid used in is unlikely to be invasive, and in addition has effective pollen control technology, and has no native species with which to cross. In addition, a body of knowledge from growers on millions of acres in Brazil and other countries experienced with the hybrid has demonstrated that the species is non-invasive, and any concerns about hydrology can be readily managed. Still BRS is seeking precautionary levels of evidence. The only way to provide such evidence is through large-scale, long-term field trials. However, here in the U.S., especially with the conditions and limitations imposed as a "regulated article" under BRS' authority this would be economically impossible for a small company like ArborGen to support unless a commercialization option is made available, predictable and efficient.

Creating a Learn-As-You-Grow-Bioeconomy

A major source of the difficulty BRS is experiencing with Freeze Tolerant Eucalyptus is that it seemingly has only one track for all products to filter through its system. "One size fits all" does not apply easily to the abundance of variation in the plant and animal kingdom, so what has worked for soybeans does not work as well for trees. As a result the soybean, a crop that is planted in the spring and harvested in the fall, has multiple advantages over perennial trees that take years to mature: 1) BRS is familiar with soybeans (even though, like Eucalyptus, it is non-native to the US), 2) because soybean plants have been deregulated previously, 3) because USDA has institutional experience with soybean production, and 4) because the public is familiar with biotech soybean.

For trees, on the other hand, the data requirements and timelines are already extended simply due to a lack of practical knowledge and familiarity at BRS with the planting and harvest of trees. Time and scale

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becomes an almost insurmountable barrier to the regulatory process for trees. BRS "wants to know what it doesn't know, but doesn't know what it doesn't know". However, such exploration, while completely acceptable for scientific investigation, is lethal for a business endeavor. BRS is not charged by the government to engage in research, but to determine if existing research meets enough criteria to be deregulated. So when BRS seeks data to satisfy NEPA or the Plant Pest Risk Analysis on novel applications, the financial burden of long term, sustained research, under permit and evaluation, over multiple years before the process can move along is beyond daunting for investors.

Therefore ArborGen proposes a track that would allow a company to take a longer path to full deregulation, if and where absolutely necessary, working closely with BRS to "answer what it doesn't know" over time. The upside would be that companies taking this track would enter into a regulated commercialization agreement with growers at a scale that allows for meaningful data collection at a landscape level, and providing some return for the expense of research and development. The collection of data then becomes collaboration between government and a healthy industry, rather than an endurance test to see if a small company can financially survive the regulatory process.

Some of the criteria for a "learn-as-you-grow-track" already exist within the Part 340 Regulations, but have not been called upon as steps required for deregulation of the more familiar agricultural crops. As a result, concepts like partial deregulation and large scale permits have only rarely been used, so the agency doesn't have a "best practices" manual or even a simple "how to" guide to help staff administer these steps, which results in delays from yet another source.

Learn-as-you-grow would allow companies to enter into agreements with growers willing to take the extended risk and reap the expected rewards, while the government maintains oversight and continues to receive data from the developer. In other words, companies would be allowed to sell the plants to growers, work with growers and the government to extract important data, and then allow harvest of the trees at maturity to be sold for uses such as bioenergy, biofuels and paper products.

The result of such a system would allow a modest income stream to help offset the cost of production and research and development, it would allow for the long-term collection of important data without punitive action stopping the process, it would establish permission for large scale demonstration level plots to be planted and observed, and it would ensure that companies can continue to innovate and explore solutions to help meet demand for renewable energy and industrial raw material.

In practice, ArborGen and Biotechnology Regulatory Services are already exploring this second track for deregulation, although our discussions have not been identified as a second 'track'. However, it is patently clear that BRS wants additional long term data on this plant and that these data requirements exceed anything that has been previously required in a deregulation petition. It is equally clear that in at least two instances (invasiveness and absolute proof of pollen control) the agency is asking ArborGen to provide evidence of something that doesn't exist. Science cannot prove a negative, but over time, it is possible to rule out the negative on the weight of evidence that it has not occurred. ArborGen believes that in the case of Freeze Tolerant Eucalyptus, there is sufficient evidence to proceed with deregulation, but BRS is reacting from a lack of institutional knowledge and choosing instead to plunge headlong into the deep well of the precautionary approach in response to environmental groups who oppose biotechnology on an ideological level.

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ArborGen's Experience is Daunting to Innovators Who Would Follow

Research in forest biotechnology has become so difficult to conduct that leading academics in the field have stopped or limited their research in these important categories. Steven Strauss, PhD, of Oregon State University, along with prominent academicians Roger Sedjo, PhD, of Resources for the Future, and Mikaela Schmitt, PhD at the University of Indiana, sent up a distress call in the 2009 edition of *The Journal of Forestry*[4]:

> *Despite many dozens of research projects, hundreds of field trials, and a long-commercialized fruit tree, virus-resistant papaya, there continue to be very little public or private sector activity in the United States that is directed toward development of transgenic forest trees. We therefore undertook a survey of scientists knowledgeable in forest biotechnologies, breeding, ecology, and regulation to assess if they believed that the regulatory regime in the United States presents a significant obstacle to research or commercial development. Conducted in 2007, there were a total of 90 respondents (60% response rate) from throughout the United States. The large majority believed that regulations, in particular containment requirements during field evaluation, posed significant obstacles to development. Top priorities for research included development of gene containment methods and field studies of wood and abiotic stress modification. Priorities for regulatory reform included development of a tiered system and provisional authorizations to enable long-term field research.*

Currently research in tree biotechnology specifically aimed at the production of biomass for biofuels and bioenergy are limited to a small number of collaborations. ArborGen is involved in many of the funded joint projects, including the collaborations with the following institutions: Joint Bioenergy Institute (JBEI), Noble Foundation, University of Georgia, Clemson University, Mendel Biotechnology, Michigan Tech University, Oregon State University, North Carolina State University, University of Florida, and a USDA National Institutes of Food and Agriculture (NIFA) grant collaboration managed by the University of Tennessee. However, the research funded by NIFA is aimed primarily at production and harvest methods, not specifically at continuing or encouraging the vital research in tree biotechnology that can significantly impact a U.S. bioeconomy by ensuring a renewable biomass supply.

The time frame for environmental impact studies and environmental analysis alone requires an enormous commitment of time and money on behalf of the U.S. government as well as industry. The most troubling aspect of these studies for academics and companies (as should be for a budget conscious Federal government) is a highly unpredictable time frame that may allow the process to drag on for years. Perhaps the most immediate solution, other than amending or changing NEPA for clarity, would be for BRS to privatize the work of the studies themselves. Hiring private commercial or academic investigators to conduct these critical environmental studies may be a solution. Privatization will automatically make the completion of such reports a priority to the investigator, and perhaps some combination of public and private resources would ensure that the work gets done in a timely manner and without delays created by lack of funding, staffing or expertise with Biotechnology Regulatory Services.

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[4] Strauss, S; S. Sedjo and M. Schmitt, 2009, ""Forest Scientist Views of Regulatory Obstacles to Research and Development of Transgenic Forest Biotechnology," *The Journal of Forestry*, Vol. 107, pp 350-357

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Conclusion

ArborGen is supportive of environmental safeguards and ensuring that new technologies are safe to humans, animals and other plants. As an example of our commitment the company perfected a pollen control technology to help minimize any perceived impact to the environment just to ensure that every precaution was followed in developing Freeze Tolerant Eucalyptus. However, we believe that the body of knowledge developed over decades within the biotechnology industry should be ample evidence to make deregulation of new organisms relatively predictable and timely. The safety record of biotech crops is unmatched.

More applications are being submitted, more novel technology is being explored, and in spite of an enormously successful track record, the United States appears to be drawing ever closer to a precautionary approach, which requires proof of damage that has not occurred – proof that something does not exist, a scientific impossibility.

Because of this drift toward ideology and away from science, it is more difficult today to get even a familiar annual crop deregulated in a timely manner. The process is greatly magnified for crops with which Biotechnology Regulatory Services and the United States Department of Agriculture lack institutional knowledge or experience. For a highly versatile perennial crop that can provide a sustainable, renewable source for industrial raw material, such as Freeze Tolerant Eucalyptus, a different track must be developed to allow for commercialization. If our leadership is unable to learn-as-it-grows with crops that may take a decade to mature, then the burden of regulatory oversight and the cost of litigation will prohibit innovation in the United States and more technology will go off shore where it can thrive.

We sincerely appreciate your consideration of this submission, and we, at ArborGen, would welcome the opportunity to discuss our proposal in greater detail with you or the professional staff at OSTP should such opportunity present itself.

Respectfully submitted,

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On Behalf of ArborGen Inc.

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